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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,577	03/02/2004	Hans-Ullrich Huth	2003DE413	3087

7590 12/23/2004

Clariant Corporation
Industrial Property Department
4000 Monroe Road
Charlotte, NC 28205

EXAMINER

REDDICK, MARIE L

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/791,577

Applicant(s)

HUTH ET AL.

Examiner

Judy M. Reddick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 8, 15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 & 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. The amendment + Counsel's persuasive arguments filed on 10/06/04 are sufficient to overcome the rejection under 35 USC § 112, 2nd paragraph as applied to claims 1-6 & 9-14 (07/27/04, paragraph no. 13. A), B), D) & E), the rejection under 35 USC 102 (b)/103 (a), as applied to claims 1-6 & 9-14, over each of Takizawa et al '089 and Takizawa et al '233, (07/27/04, paragraph no. 16) and the rejection under 35 USC 102 (b)/103 (a), as applied to claims 1-6 & 9-14, over Roreger et al (paragraph no. 17).

Election/Restrictions

2. Newly submitted claims 17 & 18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally presented invention is drawn to a composition vs. the newly presented claims (17 & 18) which are drawn to a capsule or film. The inventions are separate and distinct, each from the other as per having been related as mutually exclusive species in an intermediate-final product relationship. The intermediate product (composition) is deemed to be useful to make other than the final product (17 & 18) such as a hydrogel-containing skin adhesive. The intermediate product (originally presented invention) is in mutually exclusive relationship with the final product (newly presented invention) as per presumably a reaction takes place upon formation of the capsule or film engendering a final product structurally different from the intermediate product, i.e., the intermediate product loses its identity upon formation of the final product. Moreover, applicant himself has identified two distinct uses of the polymeric composition (film or capsule) thereby substantiating the Examiner's position.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17 & 18, along with non-elected claims 8 & 15, have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

3. The amendment filed 10/06/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added

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material that is not supported by the original disclosure is as follows: LAMEPON S (potassium cocoyl hydrolyzed collagen), page 3 (both occurrences).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

5. Claims 1-6 & 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "average molecular weight" per claim 1 constitutes indefinite subject matter as per it not being readily ascertainable if "weight average" or "number average" is intended, the two being substantially different as would be substantiated by any basic Polymer Chemistry textbook.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6 and 9-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coffin et al (U.S. 5,646,206).

Coffin et al disclose water-soluble compositions and film therefrom wherein said compositions are defined basically as containing a blend of poly (vinyl alcohol), pectin and optionally, plasticizer(s). Coffin et al specifically teach that, for useful films, the content of PVOH, in the pectin/PVOH blend, is about 10 % (w/v) to about 90 % (w/v), the molecular weight of the PVOH is about 10,000 to about 186,000 and the degree of hydrolysis of the PVOH is from about 80 to 100 %. Coffin et al further teach six samples of pectin/PVOH blends wherein the blends contained 10, 30 and 50 wt. % of PVOH at various molecular weights. See, the Abstract, col. 1, lines 10-35, col. 2, lines 7-9, col. 2, lines 53-65, col. 3, lines 47-67, col. 4, lines 7-40, col. 5, lines 7-25, col. 7, lines 56-65 and the claims of Coffin et al. Coffin et al therefor anticipate the instantly claimed invention with the understanding that the water-soluble compositions of Coffin et al overlap in scope with the claimed water-soluble compositions. It appears that all of the claim limitations are met by the disclosure of Coffin et al.

It has been held that where applicants claims a composition in terms of function, property of characteristic where said function is not explicitly shown by the reference and where the Examiner has explained why the function, property or characteristics is considered inherent in the prior art, it is appropriate for the Examiner to make a rejection under both the applicable sections of 35 USC 102 and 35 USC 103 such that the burden is placed upon applicant to provide clear evidence that the respective compositions do, in fact, differ as provided for under the guise of *In re Best*, 195 USPQ 430, 433(CCPA 1977); *In re Fitzgerald et al*, 205 USPQ 594.

As to the dependent claims, if not taught or suggested, the limitations would have been obvious to the skilled artisan and with a reasonable expectation of success, i.e., any additional or particular claim parameters which may not be specifically set out in the references are considered to be inherent in the reference products or not to involve anything unobvious absent a showing to the contrary.

As to the "consisting essentially of" clause, such limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition (*Ex parte Davis*, 80 USPQ 448, PTO Bd. App. 1948 & *In re Janakirama-Rao*, 317 F2d 951, 137 USPQ 893, CCPA 1963).

Even if it turns out that the claims are not anticipated by the disclosure of Coffin et al, it would have been obvious to the skilled artisan to extrapolate, from Coffin et al, the precisely defined water-soluble composition, as claimed, as per such having been within the purview of the general disclosure of Coffin et al and with a reasonable expectation of success.

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this

Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-6 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over International WO 99/46329.

WO'329 teach dipping solutions defined basically as containing polyvinyl alcohol (1 to 60 wt. %), at least one hydrocolloid (0.01 to 5 wt. %) which includes polysaccharides such as pectin, 0.01 to 1 % by weight of at least one sequestering agent, cation(s) and other conventional additives such as antifoaming agents. WO'329 more specifically teaches PVA capsules derived from aqueous solutions containing 2 to 7 wt. % of water, 90 to 97 wt. % of PVA, 0.01 to 10 wt. % of hydrocolloid, 0.001 to 5 wt. % of cations and optionally, 0.001 to 5 wt. % of sequestering agents and other conventional additives such as plasticizers. See the Abstract, pages 5 & 6, the Runs and claims of WO'329.

The disclosure of WO'329 differs basically from the claimed invention as per the non-specificity with respect to the polyvinyl alcohol component, in terms of molecular weight and degree of hydrolysis, as claimed. However, the polyvinyl alcohol component of WO'329 is generic thereto and therefore necessarily implies that any polyvinyl alcohol

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component, including the claimed polyvinyl alcohol component, would have been operable within the scope of patentees invention and with a reasonable expectation of success. Moreover, the use of any commercially available polyvinyl alcohol component, meeting the claimed polyvinyl alcohol limitations, in lieu of the polyvinyl alcohol component of WO'329, would have been obvious to the skilled artisan and with a reasonable expectation of equivalent results. Criticality for such, commensurate in scope with the claims, not having been demonstrated on this record.

Response to Arguments

13. Applicant's arguments with respect to claims 1-6 & 9-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. The prior art to Ibrahim et al (U.S. 5,272,191) is cited as of interest in teaching water-soluble compositions comprising polyvinyl alcohol and is considered merely cumulative to the prior art supra.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

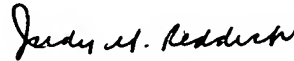
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571) 272-1110. The examiner can normally be reached on 6:00 a.m. - 2:30 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR 
12/21/04